GIBBONS

WILLIAM P. DENI, JR.
Director

Gibbons P.C.
One Gateway Center
Newark, New Jersey 07102
Direct: (973) 596-4853 Fax: (973) 639-8373
wdeni@gibbonslaw.com

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VIA ECF

Honorable Tonianne J. Bongiovanni, U.S.M.J.
United States District Court
District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608

Re: *Arbutus Biopharma Corp., et al. v. Pfizer Inc., et al.*, Civil Action No. 23-1876 (ZNQ) (TJB)

Dear Judge Bongiovanni:

This firm, along with Paul Hastings LLP, represents Defendant BioNTech SE ("BioNTech") in the above-referenced action. Consistent with Your Honor's guidance during the June 5 status conference, we write on behalf of BioNTech and Defendant Pfizer Inc. ("Pfizer," and together with BioNTech, "Defendants") to respectfully request an order compelling Plaintiffs to make a fulsome production in response to the below-identified requests for production, which seek relevant documents and things probative of Defendants' defenses and counterclaims in this action.

Through this suit, Plaintiffs Arbutus Biopharma Corp. ("Arbutus") and Genevant Sciences GmbH ("Genevant," and together with Arbutus, "Plaintiffs") seek to profit from work they did not perform and technology they did not invent. In 2020, Defendants BioNTech and Pfizer partnered to bring a reality-transforming COVID-19 vaccine to market, eventually approved as Comirnaty®. Comirnaty® is an mRNA vaccine formulated in a lipid nanoparticle delivery system; BioNTech designed the mRNA, and the lipid nanoparticle formulation used in Comirnaty® was designed by and licensed from Acuitas Therapeutics, Inc. ("Acuitas"). Plaintiffs played no role in the development of Comirnaty®. Despite that fact, Plaintiffs opportunistically seek to profit from the success of Comirnaty®, asserting five patents (across two patent families that date back to 2002 and 2008, respectively) against Defendants and alleging that Comirnaty® infringes those asserted patents. The asserted patents, however, do not claim the specific composition or lipid nanoparticle formulation of Comirnaty®—nor could they, having been filed more than a decade before either Comirnaty® or Acuitas's proprietary lipid nanoparticle formulation was developed.

Rather, Plaintiffs now attempt to leverage overbroad patents that should not have been granted to preempt the field of nucleic acid therapeutics. Plaintiffs self-style themselves as having "invented and [having been] awarded numerous patents on the breakthrough lipid nanoparticle ('LNP') technologies needed to deliver messenger ribonucleic acid ('mRNA') therapeutics to cells," but the patents-in-suit do not disclose a single working example of any mRNA molecule formulated in a lipid nanoparticle delivery system. (*See* ECF. No. 1, ¶ 1; ECF. No. 17, ¶¶ 54-55, 64, 128 (explaining that the specifications of the patents-in-suit exemplify using short interfering

RNA molecules, not messenger RNA molecules.) Instead, the patents-in-suit broadly claim, for instance, any "[n]ucleic acid-lipid particle comprising: (a) a nucleic acid" formulated using broad categories of lipids at broad percentage ranges. (*See, e.g.*, U.S. Patent No. 8,492,359 at claim 1.)

Defendants have pleaded that the asserted claims of the patents-in-suit are invalid and not infringed, as well as misused by Plaintiffs in this action; thus, Defendants are entitled to relevant documents responsive to their properly propounded discovery requests, which relate directly to Defendants' defenses and counterclaims in this action. After multiple rounds of meeting-and-conferring, Plaintiffs continue to refuse to produce relevant, responsive documents. Defendants now make this submission in accordance with Your Honor's instructions during the June 5 status conference.

A. Plaintiffs Refuse to Produce Relevant, Responsive Documents from the Moderna Litigation[1] (RFP No. 24)

This action was not the first attempt by Plaintiffs to leverage the patents-in-suit (or patent family members thereof) into an unearned windfall. Before bringing this suit, Plaintiffs sued Moderna, Inc., manufacturer of the Spikevax® vaccine, and that case is captioned *Arbutus Biopharma Corp. v. Moderna Inc.*, No. 22-252 (D. Del.). There, Plaintiffs have asserted three of the same patents-in-suit, as well as three additional family members to the patents-in-suit.[2] Each and every patent asserted in the Moderna Litigation is either at issue here, or a family member of a patent at issue here with the same specification and subject matter.

Recognizing the significant overlap in the two proceedings—*i.e.*, Plaintiffs alleging infringement of the same patents based upon a COVID-19 vaccine—Defendants served Request for Production No. 24, which requests, *inter alia*, "[a]ll documents and things produced by Plaintiffs in the Moderna Litigation." Given the identity of patents between cases, the documents produced by Plaintiffs in the Moderna Litigation are necessarily relevant to the claims and defenses

[1] "Moderna Litigation" is defined in Defendants' First Set of Requests for Production as "the lawsuit captioned *Arbutus Biopharma Corp. and Genevant Sciences GmbH v. Moderna Inc. and ModernaTX, Inc.*, No. 22-252 (D. Del.) pending in the United States District Court for the District of Delaware, or any such amended caption that should be later adopted." (Ex. A at 4.) Defendants apply the same definition here.

[2] The three overlapping patents asserted in both actions span the two patent families at issue in this case. U.S. Patent Nos. 8,492,359 and 11,141,378 (alleged priority to April 15, 2008), as well as U.S. Patent No. 9,504,651 (alleged priority to June 28, 2002), are asserted in both the Moderna Litigation and this case. The remaining patents asserted in the Moderna Litigation are each family members to those asserted here, all claiming priority to the same April 15, 2008 provisional application: U.S. Patent Nos.: 8,058,069, 8,822,668, and 9,364,435.

in this case, and Plaintiffs are obligated to produce them. [redacted] laintiffs have not offered any explanation or justification for so limiting the scope of Moderna Litigation documents that they will provide.

The indisputable overlap in asserted patents and patented subject matter between this case and the Moderna Litigation renders the full scope of documents responsive to Defendants' RFP No. 24 relevant to the claims and defenses in this case. "[W]ith regards to discovery of documents from other litigation, the appropriate standard for determining the relevance of documents from those other cases turn[s] on the similarity between the patents in the disputes. To satisfy the standard, the other case must involve the patents-in-suit or patents covering the same or similar technologies, features, or designs as the patents-in-suit." *Apple Inc. v. Samsung Elecs. Co. Ltd.*, No. 12-CV-0630-LHK PSG, 2013 WL 3246094, at *20 (N.D. Cal. June 26, 2013). Documents from the Moderna Litigation comfortably satisfy this standard,[3] as the asserted patents here are the same patents as, or patent family members of, the patents asserted in the Moderna Litigation. Plaintiffs' expert reports, contentions, and discovery responses in the Moderna Litigation are relevant to Defendants' invalidity defenses and counterclaims, as well as to Plaintiffs' claim for monetary damages. Likewise, the testimony of Plaintiffs' witnesses, including as to the alleged work underlying the patents-in-suit, are also relevant to both Defendants' invalidity defenses and counterclaims and Plaintiffs' claim for damages. Defendants have a right to understand Plaintiffs' positions with respect to the same asserted patents (or patent family members), including whether Plaintiffs are taking inconsistent positions about the same patents in different litigations. Plaintiffs should be compelled to produce from the Moderna Litigation, in addition to their Bates-stamped production, all: deposition transcripts of Plaintiffs' fact and expert witnesses, discovery responses, validity and invalidity contentions, and expert reports.

B. Plaintiffs Refuse to Produce Relevant and Responsive "Research and Development Documents" (RFP Nos. 1, 7-11, 13-18, 20-22, 26, 32, 39, 42, 56-61)

As noted above, the overbroad asserted claims of the patents-in-suit are not limited to a specific nucleic acid payload formulated in a lipid particle. Nor are the claims limited to

[3] Once the overlap in patents and patented subject matter is established, the scope of relevant documents is broad. The court in *Apple* summarized that where, as here, the asserted patents overlap in such a manner, "a presumption of relevance for all documents in [the related litigation] arises. To meet the technological nexus—and to enjoy that presumption—the patents in the two cases must meet a high degree of similarity. But once that similarity is shown, the court is justified in presuming the documents produced in litigation involving such similar patents falls within the broad scope of relevance under Rule 26(b)." *Apple*, 2013 WL 3246094, at *20.

formulations known as of the respective 2002 and 2008 priority dates [redacted] This incongruous production is improper, and Defendants are entitled to the full scope of requested responsive documents, which are relevant to Defendants' invalidity and misuse counterclaims.

Defendants propounded a number of discovery requests to which Plaintiffs have stated that they will produce "R&D Documents"—defined unilaterally and restrictively by Plaintiffs—including Requests for Production Nos. 1, 7-11, 13-18, 20-22, 26, 32, 39, 42, 56-61, which relate to the asserted patents and products embodying the asserted claims. Through meet-and-confer correspondence and negotiations, Plaintiffs identified the following as the "categories of potentially responsive non-custodial R&D Documents" that they are willing to produce:

[redacted]

(Ex. B at 1 (June 3, 2024 Email from N. Felice).) Plaintiffs' self-identified categories are improperly restrictive for at least three reasons.

First, while Plaintiffs' unilaterally-narrowed first category of "R&D Documents" includes [redacted] Such research is likely to be relevant to at least invalidity. Indeed, Defendants explained in their L. Pat. R. 3.3 invalidity contentions that declarations submitted "during prosecution of the '651 patent . . . concerning the '171 patent did not properly compare the teachings of the prior art to the claimed invention." Plaintiffs cannot withhold other experiments comparing the prior art to the claimed invention if such experiments were performed.

Second, Plaintiffs' third and fourth categories of "R&D Documents" are improperly limited to [redacted] despite the fact such other forms are plainly encompassed by the asserted claims of the patents-in-suit. Plaintiffs have provided no basis for limiting its production of "R&D Documents" to [redacted] when the patent claims are not so limited. As noted previously, Plaintiffs asserted claims are directed to any "nucleic acid-lipid particle," [redacted] For example, claim 1 of U.S. Patent No. 8,492,359, is directed to, *inter alia*, "1. A nucleic acid-lipid particle comprising: (a) a nucleic acid." The patent provides a broad definition of "nucleic acid," reading:

> The term "nucleic acid" as used herein refers to a polymer containing at least two deoxyribonucleotides or ribonucleotides in either single- or double-stranded form and includes DNA and RNA. DNA may be in the form of, e.g., antisense molecules, plasmid DNA, pre-condensed DNA, a PCR product, vectors (P1, PAC, BAC, YAC, artificial chromosomes), expression cassettes, chimeric sequences, chromosomal DNA, or derivatives and combinations of these groups. RNA may be in the form of siRNA, asymmetrical interfering RNA (aiRNA), microRNA (miRNA), mRNA, tRNA, rRNA, tRNA, viral RNA (vRNA), and combinations thereof. (U.S. Patent No. 8,492,359 at 10:26-36.)

Defendants have explained that the broad asserted claims are invalid, including under Section 112 for lack of enablement and written description. Defendants are entitled to the full scope of requested documents [redacted] which are relevant to show, for instance, inoperative embodiments, that the patent does not disclose a representative number of species falling within the scope of the asserted genus claims, and that undue experimentation would have been required to practice the unbounded claims as of the respective filing dates.

Third, Plaintiffs' second and third categories of "R&D Documents" are improperly limited [redacted] excise relevant documents and are improper.

[redacted] is improper and inappropriately limiting. It is well established that evidence after the priority date of patent applications can be used to demonstrate non-enablement and lack of adequate written description. *See, e.g.*, *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1375 (Fed. Cir. 2017) ("As explained above, the use of post-priority-date evidence to show that a patent does not disclose a representative species of a claimed genus is proper. It was thus legal error for the district court to categorically preclude

all of Appellants' post-priority-date evidence [of other later-arising embodiments of the claim]."); *id.* ("For many of the same reasons, the district court's improper exclusion of post-priority-date evidence requires a new trial on enablement as well . . . . Appellants purportedly sought to introduce post-priority-date evidence showing that Appellees engaged in lengthy and potentially undue experimentation to enable the full scope of the claims. Such evidence could have been relevant to determining if the claims were enabled as of the priority date and should not have been excluded simply because it post-dated the claims' priority date."). Defendants have explained that the asserted claims are invalid, including under Section 112 for lack of written description and lack of enablement. Defendants are entitled to research and development documents relevant to these defenses, including post-priority documents not limited by date restriction.

Further, it is inappropriate for Plaintiffs to unilaterally (and seemingly arbitrarily) limit its third category of "R&D Documents" to [redacted] Plaintiffs should produce such documents.

Mindful of Your Honor's instructions during the status conference, Defendants have extended the below compromise to Plaintiffs:

> (1) the research underlying ***all declarations*** submitted in the prosecution of the asserted patents, including applications within the same family;
>
> (2) lab notebooks and other research-related documents from named inventors from Jan. 1, 2001 ***onward***;
>
> (3) documents related to Protiva and/or Tekmira's research and development efforts concerning ***any LNP formulations*** within the scope of any asserted claim of the patents-in-suit; and
>
> (4) study reports relating to Genevant's research and development efforts concerning lipids or LNP formulations for use with or comprising ***nucleic acids***, which are within the scope of any asserted claims of the patents-in-suit.

[4] This shortcoming thus overlaps with the second flaw of Plaintiffs improperly limiting their responses to mRNA.

(Ex. D at 3 (June 13, 2024 Letter from S. Kung).) Plaintiffs have not yet responded to Defendants' compromise proposal sent on June 13, 2024; to the extent Plaintiffs decline to voluntarily make this reasonable scope of production, they should be compelled to do so.[5]

C. Plaintiffs Refuse to Produce Relevant and Responsive COVID-19 Vaccine Development Documents (RFP No. 61)

As noted above, Defendants (together with partners like Acuitas)—but not Plaintiffs—successfully brought a COVID-19 vaccine to market to quell the once-in-a-generation pandemic. It is not clear, though, whether Plaintiffs attempted to design (whether on their own or with a partner) a COVID-19 vaccine that would fall within the broad scope of the asserted claims. Any failed efforts by Plaintiffs to design a successful COVID-19 vaccine that would fall within the scope of the asserted patent claims bears on Defendants' pleaded invalidity defenses, as well as Plaintiffs' claim for damages. Accordingly, Defendants propounded Request for Production No. 61, which directs Plaintiffs to produce "documents and things concerning any contemplated, planned, and/or initiated effort(s) by Plaintiffs, alone or in collaboration with any other entity or entities, to develop any vaccine, drug product, and/or therapy related to SARS-CoV-2." (Ex. A at 20.)

[redacted] will exclude documents that are relevant to Defendants' invalidity and damages positions. Defendants have offered a compromise that Plaintiffs produce non-public documents concerning Plaintiffs' efforts to develop a SARS-CoV-2 vaccine within the scope of any asserted patent claim. (Ex. D at 3.) Plaintiffs have not yet responded, but should they reject this compromise, the Court should compel Plaintiffs to produce such documents.

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[5] With respect to the starting date of Plaintiffs' second category above, [redacted] the right to raise any issue after reviewing Plaintiffs' production and as discovery progresses.

[redacted]

D. Plaintiffs Refuse to Produce Relevant and Responsive Third-Party Documents (RFP No. 25)

Plaintiffs have painstakingly avoided agreeing to produce the full scope of documents that they have received or may receive from third parties relevant to Plaintiffs' or Defendants' claims and defenses. In particular, Defendants propounded Request for Production No. 25, which is directed to, *inter alia*, "documents and things produced by third parties in" this action in order to ensure that Defendants receive all third-party materials that Plaintiffs obtain so there is a level playing field. (Ex. A at 12.) However, [redacted] Plaintiffs have not offered any rationale or basis for this narrowed formulation, which notably would exclude [redacted] they deem to fall outside of the (narrowed) scope of what they have otherwise agreed to provide. Plaintiffs should not be allowed to withhold relevant third-party documents and benefit from any information asymmetry, and so they should be compelled to produce all relevant documents received from third-parties in this action.

E. Plaintiffs Refuse to Produce Relevant Clinical and Pre-Clinical Testing Documents (RFP Nos. 9-11, 13)

Through RFP Nos. 9-11 and 13, Defendants requested relevant documents relating to preclinical and clinical testing of compositions or products within the scope of any asserted claims of the patents-in-suit. Plaintiffs, however, have again improperly and unilaterally narrowed the scope of documents they will produce in response to these requests, agreeing to provide only:

[redacted]

(Ex. B at 12.) Plaintiffs' self-identified categories for these requests are improperly restrictive for similar reasons as discussed above with regard to Plaintiffs' unilateral formulation of "R&D Documents" it would produce.

As discussed above [redacted] when the asserted claims are not so limited, and there is no basis to impose the listed date range limitations. The full scope of responsive documents is relevant to, at least, objective indicia of non-obviousness of the asserted patents, Plaintiffs' claim for damages, as well as Defendants' defenses of invalidity, including based on lack of adequate written description and lack of enablement. Defendants are entitled to the full scope of requested documents and Plaintiffs should not be permitted to unilaterally narrow the requests and withhold documents. Nevertheless, in line with the compromise proposal laid out above for "R&D Documents" and RFP Nos. 1, 7-11, 13-18, 20-22, 26, 32, 39, 42, 56-61, Defendants extended the following compromise position tethered to the scope of the claims that Plaintiffs have asserted:

> Genevant's R&D concerning lipids or LNP formulations for use with or comprising nucleic acids, which are within the scope of any asserted claim of the patents-in-suit; and Plaintiffs' R&D documents, as defined by Defendants' above proposal, *i.e.*,
>
> > (1) the research relating to any declaration submitted during prosecution of any of the applications for the patents-in-suit, including applications within the same families;
> >
> > (2) lab notebooks and other research documents from named inventors from Jan. 1, 2001 onward;
> >
> > (3) documents related to Protiva and/or Tekmira's research and development efforts concerning lipids or LNP formulations for use with or comprising nucleic acids, which are within the scope of any asserted claim of the patents-in-suit; and
> >
> > (4) study reports related to Genevant's research and development efforts concerning lipids or LNP formulations for use with or comprising nucleic acids, which are within the scope of any asserted claim of the patents-in-suit.

Plaintiffs have not yet responded to this compromise offer, but should Plaintiffs reject Defendants' compromise, Plaintiffs should be compelled to make such production.

Defendants respectfully thank Your Honor for consideration of this motion.

Respectfully submitted,

s/ William P. Deni, Jr.
William P. Deni, Jr.

cc: All counsel of record (via ECF)